TRIALS

Clinical trials are carefully controlled and **federally monitored** research studies on drugs, procedures or other treatments that must pass

rigorous testing before they are granted government approval.



How do clinical trials work?



THE GOAL

THE PROCESS

Before a clinical trial can be conducted on

laboratory, on **cells** and **animals**.

people, the research is tested thoroughly in a

If the U.S. Food and Drug Administration (FDA)

grants permission to conduct the study on

people, the clinical trial stage is generally

performed in four steps, or phases.

To determine whether:

- **Existing treatments** can be used in new ways
- **New treatments** work better than standard therapies

THE RESEARCH **Researchers study**

whether the treatments:

- Are effective in treating cancer
- Work better than existing therapies used to treat a particular cancer
- + Are safe for patients
- + Cause side effects, and if so:
 - Identify side effects
 - Measure how severe they are







GOAL To determine the safest maximum dose

PHASE

To determine safety and effectiveness

PHASE

the new treatment works better than existing treatments

To determine whether

safety and effectiveness, once FDA-approved



LENGTH

10 to 30 people

Several months

to 2 years

30 to 120 patients

Several months

1 to 4 years

for market Several years

To measure long-term



SUCCESS

RATE



About 25-30% of drugs

More than 300 patients







About 70% of drugs



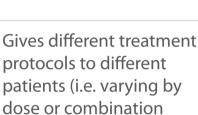
move to approval









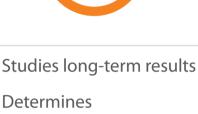


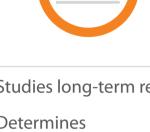
1. Control group (getting the standard treatment)

May divide patients into

two groups:

- 2. Study group (getting the new treatment)
- (doctors do not choose which patients get which







over time Determines how the

treatment should be

delivered (i.e. orally,

intravenously)

of therapies) Measures the treatment's impact on a certain cancer

Are typically randomized

treatments)

cost-effectiveness Collects information on

side effects

placebos?

What about

when no standard treatment exists. In all other cases, rather than a placebo, control group patients receive the standard treatment for comparison.

treatments) are very rarely used in cancer treatment clinical trials, and only

While common in other areas of research, placebos (inactive drugs or

qualifies for clinical trials?

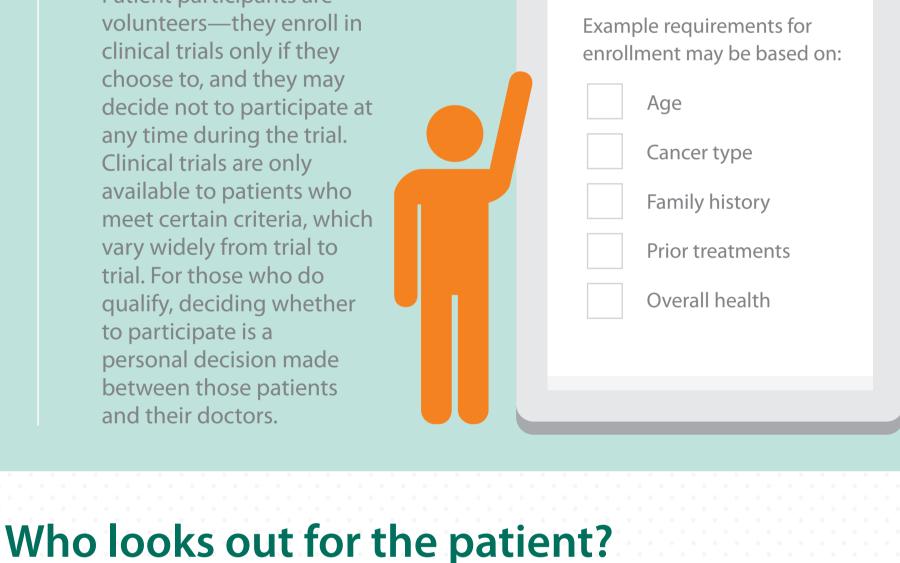
Who

choose to, and they may decide not to participate at any time during the trial. Clinical trials are only available to patients who meet certain criteria, which vary widely from trial to trial. For those who do qualify, deciding whether to participate is a personal decision made between those patients and their doctors.

Patient participants are

clinical trials only if they

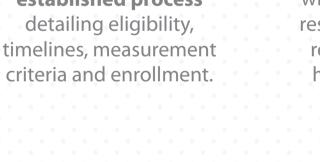
volunteers—they enroll in

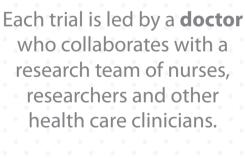


A clinical trial must meet a set of rigorous standards to protect participating

patients and ensure the study's results are accurate and comprehensive.









community leaders. What are the benefits and risks?

side effects.

doctors, nurses, lawyers, patient advocates and other



records involved.

trial may help patients by: clinical trial may include: Offering access to treatments that may not

experts who are closely monitoring their progress and overall health • Delivering personalized, expert care

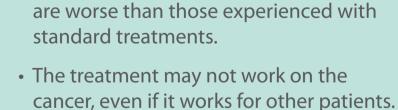
specific to their disease

have otherwise been available to them

Providing the support of a team of cancer

Participating in a clinical

- Providing comfort in knowing that their participation may benefit other cancer patients
- - The smallest **number of patients**



• The treatment may not result in better

outcomes than standard treatments.

Risks of participating in a

The treatment may cause unexpected

• Patients may experience side effects that

Clinical trials by the numbers

abnormalities.)

needed for a clinical trial (Also called N=1, or "the N of 1," single-participant trials are a growing trend in the field of genomic medicine, which analyzes the unique mutations that may be driving a patient's tumor, in search of a treatment designed to target those

patient



years

How long a drug is

clinical trials stage

studied, on average,

before it makes it to the

years cancer drugs How long it takes, on average, from the The number of cancer time a cancer drug drugs the FDA approved enters clinical trials in 2021, following until it's approved extensive clinical trials



very strongly in clinical trials as an option for our patients. We've learned many of the things that are now standard of care from clinical trials, and I believe that is important to see if there are any potential clinical trials for a patient.

At Cancer Treatment Centers of America® (CTCA), we believe





SOURCES

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U.S. National Institutes of Health, National Cancer Institute, U.S. Food and Drug Administration, American Society of Clinical

- Pamela Crilley, DO, Chair of the

Oncology, American Cancer Society

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